EXHIBIT E

Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS)

Extended-release, long-acting (ER/LA), and immediate-release (IR) opioid analgesics, such as hydrocodone, oxycodone, and morphine, are powerful pain-reducing medications that have both benefits as well as potentially serious risks. The FDA has determined that a REMS is necessary for all opioid analgesics intended for outpatient use to ensure that the benefits of these drugs continue to outweigh the risks. The Opioid Analgesic REMS (https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm), approved on September 18, 2018, is one strategy among multiple national and state efforts to reduce the risk of abuse, misuse, addiction, overdose, and deaths due to prescription opioid analgesics.

The REMS program requires that training be made available to all health care providers (HCPs) who are involved in the management of patients with pain, including nurses and pharmacists. To meet this requirement, drug companies with approved opioid analgesics will provide unrestricted grants to accredited continuing education providers for the development of education courses for HCPs based on the FDA's Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain. (https://www.accessdata.fda.gov/drugsatfda_docs/rems/Opioid_analgesic_2018_09_18_FDA_Blueprint.pdf) The FDA believes that all HCPs involved in the management of patients with pain should be educated about the fundamentals of acute and chronic pain management and the risks and safe use of opioids so that when they write or dispense a prescription for an opioid analgesic, or monitor patients receiving these medications, they can help ensure the proper product is selected for the patient and used with appropriate clinical oversight.

There is no mandatory federal requirement that prescribers or other HCPs take the training and no precondition to prescribing or dispensing opioid analgesics to patients. However, the FDA's Opioid Policy Steering Committee (/about-fda/office-medical-products-and-tobacco/opioid-policy-steering-committee) continues to consider whether there are circumstances when the FDA should require some form of mandatory education for HCPs, and how the agency would pursue such a goal. The agency's aim is to reduce unnecessary and/or inappropriate exposure to opioids by making certain that HCPs are properly informed about appropriate prescribing recommendations, that HCPs understand how to identify abuse by individual patients, and know how to get patients with opioid use disorder into treatment.

The FDA's goal is to reduce serious adverse outcomes resulting from inappropriate prescribing, misuse and abuse of opioid analgesics, while maintaining patient access to pain medications.

Additional Resources

- FDA takes important steps to encourage appropriate and rational prescribing of opioids through approval of new safety measures for immediate-release opioid analgesic medications (/news-events/press-announcements/fda-takes-important-steps-encourage-appropriate-and-rational-prescribing-opioids-through-final)
- FDA's Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain (https://www.accessdata.fda.gov/drugsatfda_docs/rems/Opioid_analgesic_2018_09_18_FDA_Blueprint.pdf) (PDF - 141 KB)
- Opioid Medications (/drugs/information-drug-class/opioid-medications)

Background and Historical Information

- Safety Measures for Extended-release and Long-acting Opioids (/drugs/information-drug-class/new-safety-measures-announced-extended-release-and-long-acting-opioids)
- Safety Measures for Immediate-Release Opioids (/drugs/information-drug-class/new-safety-measures-announced-immediate-release-ir-opioids)
- Historical Information on Opioid Analgesic REMS (/drugs/information-drug-class/historical-information-rems-opioid-analgesics)

Back to Top